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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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10/672,215

09/26/2003

Marco Eggink

49865.1

2892

23973

7590

06/20/2006

DRINKER BIDDLE & REATH
ATTN: INTELLECTUAL PROPERTY GROUP
ONE LOGAN SQUARE
18TH AND CHERRY STREETS
PHILADELPHIA, PA 19103-6996

EXAMINER

GRAFFEO, MICHEL

ART UNIT

PAPER NUMBER

1614

DATE MAILED: 06/20/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

10/672,215

Applicant(s)

EGGINK ET AL.

Examiner

Michel Graffeo

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --
Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 9 March 2006.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-32 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-32 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|---|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date <u>3/10/06; 2/12/04</u> . | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Election/Restrictions

Applicant's election of Group 1 claims 1-32 in the reply filed on 9 March 2006 is acknowledged. Because applicant did not distinctly and specifically point out the supposed errors in the restriction requirement, the election has been treated as an election without traverse (MPEP § 818.03(a)). Claims 33-61 have been canceled.

Status of Action

Claims 1-32 are examined.

Claim Objections

Claim 1 is objected to because of the following informalities: the amount of ximenynic acid in line 3 is "from about 01. to 99.9 wt %" and to that extent the number "01." seems to be a typo. Appropriate correction is required.

Abstract

Applicant is reminded of the proper language and format for an abstract of the disclosure.

The abstract should be in narrative form and generally limited to a single paragraph on a separate sheet within the range of 50 to 150 words. It is important that the abstract not exceed 150 words in length since the space provided for the abstract on the computer tape used by the printer is limited. The form and legal phraseology often used in patent claims, such as "means" and "said," should be avoided. The abstract should describe the disclosure sufficiently to assist readers in deciding whether there is a need for consulting the full patent text for details.

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The language should be clear and concise and should not repeat information given in the title. It should avoid using phrases which can be implied, such as, "The disclosure concerns," "The disclosure defined by this invention," "The disclosure describes," etc and legal terms such as "comprises". In this case the qualifying language "Novel" and "comprises" in the first sentence is objected to.

Claim Rejections - 35 USC § 112

The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 9-14, 17-19, 22-24 and 27 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. This is a written description rejection.

Applicant has not conveyed possession of the invention with reasonable clarity to one skilled in the art. In particular, Applicant has not provided a description of the structure of a representative number of products which Applicant refers to as "derivatives", "hardened varieties" and "continuous" spreads nor a description of the chemical and/or physical characteristics of a representative number of products nor a description of how to obtain a representative number of specific products.

Claim Rejections - 35 USC § 101

35 U.S.C. 101 reads as follows:

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Whoever invents or discovers any new and useful process, machine, manufacture, or composition of matter, or any new and useful improvement thereof, may obtain a patent therefor, subject to the conditions and requirements of this title.

Claims 1-5, 15, 26 and 30 are rejected under 35 U.S.C. 101 because the claimed invention is directed to non-statutory subject matter. Claims 1-5 are directed to a composition that is naturally found in nature. See Liu et al. Separation and Identification of Trioximenynin from Santalum spicatum R. Br. "JAOCS, Vol 74 no 10(1997):1269-1272 (cited by Applicant on IDS filed 12 February 2004 #AG) which teaches that the seeds of sandalwood Santalum spicatum comprise about 40% Ximenynic acid and triacylglyceride (see Abstract). US Patent No. 4900734 to Maxson et al. also teach that santalbic is one of a group of fatty acids wherein glycerides account for 51-95 wt% of the fatty acid (see col 7 lines 30-40). Finally, regarding claim 30, to the extent that an "effective amount" is not defined, it is reasonable to interpret an effective amount to be that which is found in the sandalwood seeds and the encapsulating material is that which houses the seeds.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 1-5, 12, 15 and 18 are rejected under 35 U.S.C. 102(b) as being anticipated by Jones et al. "Santalbic acid from quandong kernels and oil fed to rats affects kidney and liver", Asia Pacific J Clin Nutr (199), Volume 8 (3), pp 211-215 (cited by Applicant on IDS filed 10 March 2006 #AB).

Jones et al. teach an absorption study wherein rats were fed quandong oil (from santalum species (claims 15 and 18) in an amount as shown in Table 2 on page 212 such that the proportion of fatty acid (santalbic acid, also known as ximenynic acid or *trans*-11-octadecen-9-ynoic acid) in the dietary lipid is 42% (claims 1-5, 12, 15 and 18) and the diet energy from the lipid is 53.2%. Experiment 2 on the same page also describes a diet of quandong kernel which comprises 56.4% lipid and of that 37.5% is santalbic acid. Therefore, Jones et al. teach a composition comprising ximenynic acid in an amount that is from 0.1 to 99.9% by weight (42% is within the range of from 0.1 to 99.9%).

Claims 1-5, 15, 26 and 30 are rejected under 35 U.S.C. 102(b) as being anticipated by Liu et al. Separation and Identification of Triximenynin from Santalum spicatum R. Br. "JAOCS, Vol 74 no 10(1997):1269-1272 (cited by Applicant on IDS filed 12 February 2004 #AG).

Liu et al. teach that the seeds of sandalwood Santalum spicatum comprise about 40% Ximenynic acid and triacylglycerid (see Abstract).

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Claims 1, 4-5 and 15 are rejected under 35 U.S.C. 102(b) as being anticipated by US Patent No. 4900734 to Maxson et al.

Maxson et al. also teach that santalbic acid (as noted above santalbic acid is also known as ximenynic acid or *trans*-11-octadecen-9-ynoic acid) is one of a group of fatty acids wherein glycerides account for 51-95 wt% of the fatty acid (see below col 7 lines 30-40). Since the santalbic acid is taught as present in an amount of from 51-95% it falls within the range claimed: from about 0.1 to 99.9 wt %.

Col 7:

product. Oils high in glycerides of polynsaturated fatty acids are particularly effective for purposes of the present invention. Such polyunsaturated fatty acids include linoleic, linolenic, santalbic, eleosoteric, punicic, trichosanin, and parinaric acids. Of the foregoing acids, linoleic and linolenic acids are particularly common in certain natural vegetable oils. Accordingly, the oily vehicle according to the present invention is preferably a natural vegetable oil consisting mainly of glycerides of fatty acids, wherein the fatty acid glycerides comprise 51-95 wt. % of glycerides of polyunsaturated acids, particularly 70-80% of glycerides of polyunsaturated fatty acids. Such natural vegetable oils include, for

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

Claims 1-19 are rejected under 35 U.S.C. 103(a) as being unpatentable over WO 02/088159 to Susilo in view of Liu et al. Separation and Identification of Triximenynin from Santalum spicatum R. Br. "JAOCS, Vol 74 no 10(1997):1269-1272 (cited by Applicant on IDS filed 12 February 2004 #AG).

Susilo teaches a drug combination comprising free fatty acids and the use of such in a drug combination wherein the combination comprises nervonic acid (Table 2 on page 4), ximenynic acid (Table 4 on page 8) and glycerides (page 8 line 2) wherein the dosage of the compounds is dependent on the subject being treated, on the subjects weight, severity of the disease etc. (see page 26 lines 1-5).

Susilo does not teach specific quantities or ratios of the above ingredients nor a source for the fatty acids. Regarding the specific quantities of the ingredients as noted above Susilo teaches that the amounts of actives can be optimized depending on particular patient specifications (claims 6-9 and 13-14).

Liu et al. teach that ximenynic acid comes from *Santalum spicatum*, a santalum species.

One of ordinary skill in the art would have been motivated to combine the above references and as combined teach the claimed invention as claimed. One of ordinary skill in the art would have been motivated to combine Susilo and Liu et al. because Susilo teaches that the fatty acids are common in seed oils (see page 4 lines 1-2) and Liu et al. teach a specific seed oil. Thus, the combined references teach and make prima facie obvious how to use the claimed invention at the time that it was made.

Claims 1-32 are rejected under 35 U.S.C. 103(a) as being unpatentable over WO 02/088159 to Susilo, as applied to claims 1-19 above, in view of US Patent No. 3047401 to Baur and further in view of Chemical Land21 <http://www.chemicalland21.com/arokorhi/specialtychem/finechem/TBHQ.htm>; Retrieved 18 May 2006.

Susilo teaches a composition formed as tablets and capsules wherein the active agent is combined with a diluent such as lactose and/or sucrose to form a powder (see page 23 lines 30-end). Susilo does not teach a confectionary food product nor an additional stabilizer.

Baur teaches that glyceride is a suitable vehicle for an all purpose culinary oil formed by dissolving certain long chain fatty acids in glyceride oil (see col 1 lines 65-70) wherein such oils can be used in baking and as a shortening (see col 1 lines 10-15 and col 1 lines 25-35).

Chemical Land21 teaches that TBHQ is a preservative for fats and oils.

One of ordinary skill in the art would have been motivated to combine the above references and as combined teach the claimed invention as claimed. One of ordinary skill in the art would have been motivated to combine Susilo and Baur because Baur teaches that the result of dissolving long chain fatty acids in glyceride oil is an all purpose clear culinary oil, and likewise, Susilo teaches that the fatty acids therein, when dissolved in glyceride result in a suppository. The success of such a combination is a motivating factor to combine the actives as claimed. Chemical Land21 teaches that TBHQ is a preservative for fats and oils and since both Susilo and Baur are directed to fats and oils from natural sources one of ordinary skill in the art would find it obvious to preserve the composition with a common preservative. As combined, the references teach a confectionary comprising the claimed components. Thus, the combined references teach and make prima facie obvious how to use the claimed invention at the time that it was made.

Claims 1-25 are rejected under 35 U.S.C. 103(a) as being unpatentable over US PreGrant Publication. 2004/0247657 to Susilo in view of US Patent No. 3047401 to Baur.

Susilo teaches a composition and combination therapy (paragraph 72) comprising glycerides (paragraph 36) present in an effective amount (paragraph 39), fatty acids such as nervonic acid and santalbic acid (see paragraph 37) present in a

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sufficient amount to produce a salt (paragraph 34), mixtures of oleic acid (paragraph 36) and oxidants such as BHT (paragraph 53).

Susilo does not recite specific quantities and ratios of the ingredients but teaches that the amounts can be manipulated. Susilo also does not teach the source of the fatty acids.

Baur teaches that glyceride is a suitable vehicle for an all purpose culinary oil formed by dissolving certain long chain fatty acids in glyceride oil (see col 1 lines 65-70) wherein such oils can be used in baking and as a shortening (see col 1 lines 10-15 and col 1 lines 25-35).

One of ordinary skill in the art would have been motivated to combine the above references and as combined teach the claimed invention as claimed. One of ordinary skill in the art would have been motivated to combine Susilo and Baur because Baur teaches that the result of dissolving long chain fatty acids in glyceride oil is an all purpose clear culinary oil, and likewise, Susilo teaches that the fatty acids therein, ximenynic and nervonic acids, when dissolved in glyceride result in a suppository. The success of such a combination is a motivating factor to combine the actives as claimed. As combined, the references teach a confectionary comprising the claimed components. Thus, the combined references teach and make prima facie obvious how to use the claimed invention at the time that it was made.

Conclusion

No claim is allowed.

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Any inquiry concerning this communication or earlier communications from the examiner should be directed to Michel Graffeo whose telephone number is 571-272-8505. The examiner can normally be reached on 9am to 5:30pm Monday to Friday.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Ardin Marschel can be reached on 571-272-0718. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

7 June 2006
MG


ARDIN H. MARSCHEL
SUPERVISORY PATENT EXAMINER